

DEC 27 2004

**510(k) Summary of Safety and Effectiveness:
T2 PHN Line Extension****Submission Information**Name and Address of the Sponsor
of the 510(k) Submission:Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, NJ 07430

For Information contact:

Vivian Kelly, Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Phone: (201) 831-5581
Fax: (201) 831-6038

Date Summary Prepared:

December 10, 2004

Device Identification

Proprietary Name:

T2 Proximal Humeral Nail

Common Name:

Intramedullary Nail

Classification Name and Reference:

Intramedullary Fixation Rod and Accessories,
21 CFR §888.3020

Device Product Code:

87 HSB

Description:

This Special 510(k) submission is a line extension to the T2 Nailing System to add a new style of Proximal Humeral Nail. The nails are inserted using an opened or closed technique and can be statically or dynamically locked. The T2 Proximal Humeral Nail is intended for single use only.

Intended Use:

The T2 Proximal Humeral Nail is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.

Statement of Technological Comparison:

The material used to manufacture the line extension to the T2 Nail System is identical to that of the predicate. FEA analysis and mechanical testing demonstrates the comparable mechanical properties of the subject T2 Nail System to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2004

Ms. Vivian Kelly
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K043404

Trade/Device Name: T2 Proximal Humeral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 10, 2004
Received: December 10, 2004

Dear Ms. Kelly:

:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

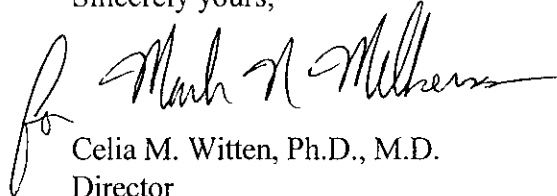
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: T2 Proximal Humeral Nail

Indications for Use:

The T2 Proximal Humeral Nail is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.

Prescription Use X

(Part 21 CFR 801 Subpart D)

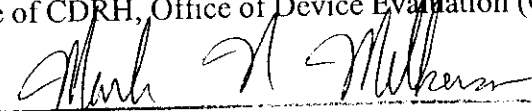
AND/OR

Over-The-Counter Use

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for 
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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